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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,094	02/08/2002	Francisco Javier Garcia-Ladona	0480/01203	5429

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER  
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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/868,094	Applicant(s) GARCIA-LADONA ET AL.	
	Examiner Jon M. Lockard	Art Unit 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-11 and 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 3,8-10 and 13-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims drawn to an invention nonelected with traverse in the reply filed 28 October 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Status of Application, Amendments, and/or Claims***

2. The amendment of 13 February 2006 has been entered in full. Claim 6 has been cancelled and claims 1, 4, 7, and 11 have been amended.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Withdrawn Objections and/or Rejections***

4. The objection to the Drawings as set forth at pg 3 of the previous Office Action (mailed 17 October 2005) is withdrawn in view of Applicants submission of a replacement sheet for Figure 1 (filed 13 February 2006).

5. The rejection of claims 1-2, 4-5, 7, and 11 under 35 U.S.C. § 112, first paragraph (Written Description) as set forth at pg 3-5 of the previous Office Action (mailed 17 October 2005) is withdrawn in view of Applicants amendments to claims 1, 4, 7, and 11 which now limits the compounds to SIB-1893 and MPEP (filed 13 February 2006).

Art Unit: 1647

6. The rejection of claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Varney et al. as set forth at pg 6-7 of the previous Office Action (mailed 17 October 2005) is moot in view of Applicants cancellation of said claim (filed 13 February 2006).

***Maintained Objections and/or Rejections***

***Claim Rejections - 35 USC § 103***

7. Claims 1-2, 4-5, 7, and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Varney et al. (1999, The Journal of Pharmacology and Experimental Therapeutics. 290:170-181 for reasons of record as set forth at pg 6-7 of the previous Office Action (mailed 17 October 2005).

8. Applicants argue at pg 6 of the response (filed 13 February 2006) that Varney et al. does not suggest the particular psychiatric disorders specifically claimed in the present application or the mechanism by which they are treated.

9. Applicant's arguments (filed 04 October 2005) as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons. It is noted that the recitation of "A method for treatment of neuroleptic malignant syndrome or psychosis in a human being" in claim 1; the recitation of "A method for treatment of neuroleptic induced disorders or psychosis in a human being" in claim 4; the recitation of "A method for treatment of neuroleptic malignant syndrome in a human being" in claim 7; and the recitation of "A method of treatment of CNS disorders in a human being via glial cells" in claim 11 has not been given patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended

Art Unit: 1647

use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, as stated at pg 7 of the previous Office Action (mailed 17 October 2005) a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). Simply stating a new property of the compound of Varney et al. (i.e., modulates homer expression, action on glial cells) does not render the compound of the instant application free of the art. Therefore, while Varney et al. do not explicitly teach administration of SIB-1893 to a human to treat neuroleptic malignant syndrome, neuroleptic induced disorders, or psychosis, they clearly suggest that administration of SIB-1893, a selective noncompetitive antagonist of human metabotropic glutamate receptor type 5 (mGluR5), may be used to treat psychiatric disorders (See pg 179).

10. Thus, the claimed invention as a whole was *prima facie* obvious over the teachings of the prior art.

### ***Summary***

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1647

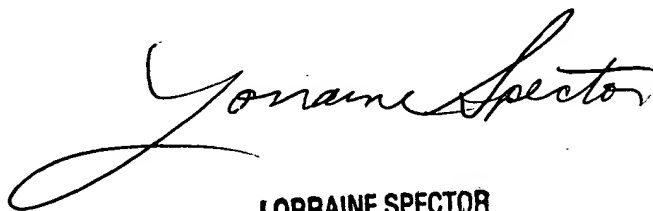
*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.  
April 20, 2006



**LORRAINE SPECTOR  
PRIMARY EXAMINER**